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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,541	04/26/2002	Larry A. Wheeler	17400(BAR)	1687

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,541	WHEELER ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,18-22 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,18-22 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/9/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Action is in response to the communication filed on 12/9/2005.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. Specifically, Applicants' have correctly pointed out that the Miller reference (U.S. 2002/0040015 A1) does not receive priority to 2/10/2000 because the provisional application (60/181,641, filed 2/10/00) does not disclose the use of an anti-apoptotic molecule. It is noted that the Miller reference does provide support for using an anti-angiogenic factor. Therefore, with respect to using an anti-angiogenic factor, Miller has an effective filing date of 2/10/2000. However, with respect to using an anti-apoptotic factor, the effective filing date of the Miller reference is 2/9/2001.

Considering that Finality has been withdrawn, the amendment filed 12/9/2005 has been entered. Claims 16, 18-22 and 30 are currently pending in the application and are addressed herein.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/9/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 18-22 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "said neuroprotectant" in line 8. There is insufficient antecedent basis for this limitation in the claim. It is noted that there is sufficient antecedent basis for "said brimonidine" and amending the claim as such would obviate this rejection.

Claims 18-22 and 30 are included in the rejection because they are dependent claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16, 18-22 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application publication No US 2002/0040015 A1 (Miller at al.) in view of U.S. Patent No. 6,180,402 B1 (Granville et al.) and further in view of Wheeler et al. (Europ. Jour. Ophthal., JAN-MAR 1999, previously of record).

It is noted that the effective filing date of the Miller reference, with respect to PDT in combination with an anti-angiogenic agent is 2/10/2000.

Miller teaches a method and composition for treating conditions of the eye. Specifically, Miller teaches a method for photodynamic therapy (PDT) of ocular conditions characterized by the presence of unwanted choroidal neovasculature which includes enhancing the PDT method by administering an antiangiogenic compound (e.g., see abstract; paragraph 18; claims 20-31, etc.). It is noted that the instant specification acknowledges it was previously known that PDT can result in optic nerve atrophy (See p. 3, first full paragraph).

Miller does not teach that the method includes the administration of the anti-apoptotic compound Brimonidine.

Granville teaches that it is beneficial to include an anti-apoptotic molecule in PDT treatments in order to ameliorate the adverse effects of PDT (e.g., see column 6, lines 46-64; column 8, lines 52-63; column 10, lines 15-50; column 11, lines 26-46; column 12, lines 15-20; claim 1; etc.). Specifically, Granville teaches a method of PDT treatment wherein an anti-apoptotic agent is used with the PDT treatment, and teaches that the PDT treatment can be for

treating conditions of the eye (e.g., see 11, lines 26-65; column 9, lines 8-15; column 10. lines 15-25; etc.)

Granville does not teach that the anti-apoptotic molecule can be brimonidine.

Wheeler teaches that Brimonidine is an alpha-2 agonist compound that is an anti-apoptotic neuroprotective agent that can inhibit apoptosis and protect ocular neural tissue as demonstrated in animal models of retinal and optic nerve injury (e.g., see page S20, second column; page S21, etc.).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time of filing to perform the method taught by Miller and to include an anti-apoptotic molecule in the treatment (as taught by Granville) and to use Brimonidine as the anti-apoptotic agent with a reasonable expectation of success.

One of ordinary skill in the art would have been motivated to use an anti-apoptotic agent in the PDT treatment because Granville teaches that it is beneficial to include an anti-apoptotic molecule in PDT treatments in order to ameliorate the adverse effects of PDT. Furthermore, one of ordinary skill in the art would have been motivated to use Brimonidine as the anti-apoptotic agent because Wheeler teaches that Brimonidine is an anti-apoptotic agent that can be used to protect target cells from neuronal injury (e.g., see page S20-S21, etc.), thus Brimonidine is an art recognized equivalent of the anti-apoptotic agents taught by Granville (see MPEP 2144.06-2144.07 regarding substitution of equivalents).

Response to Arguments

Applicant's arguments, see pages 4-8 of the communication filed 12/9/2005 with respect to the rejection(s) of the claims have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Granville et al., for the reasons indicated above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

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AU 1635